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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/073,596	05/06/1998	RALPH M. STEINMAN	20164000US5	9977

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/073,596	STEINMAN ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *82,84-96 and 98-120* is/are pending in the application.

4a) Of the above claim(s) *82,85-88,90,93,96,98,100 and 102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *84,89,91,92,94,95,99,101 and 103-120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 84, 89, 91-92, 94-95, 99, 101, and 103-120 are being acted upon.

2. Applicant's remarks/arguments, filed 11/17/04, are acknowledged. In view of Applicant's arguments, the previous rejections under 35 U.S.C. 103(a) have been withdrawn. In particular, Applicant's arguments that Sallusto et al. (1994, IDS) cannot be applied as a prior art reference have been found convincing.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 109 stands rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed, for the reasons of record. This is a new matter rejection.

As set forth previously, the specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, the recitation in Claim 109 of, "wherein the cell aggregates are subcultured about one to five times."

Applicant arguments, filed 11/17/04, have been fully considered but are not found persuasive. Applicant argues that support for the amended claim can be found at pages 43-46 and 55 of the specification.

Applicant is advised that a disclosure of subculturing at about day 10 and at about day 20, for 1-2 months, is not the same in scope as subculturing about 1 to 5 times as claimed. For example, subculturing about 1 to 5 times encompasses subculturing just once, whereas the disclosure of the specification cited by Applicant does not. Regarding the example at page 57, the citing of a specific example employing only mouse cells cannot support the broader generic claim which would encompass the use of cells from any species, including human.

5. Claims 84, 89, 91-92, 94-95, 99, 101, and 103-120 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed, for the reasons of record. This is a new matter rejection.

As set forth previously, the specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, the recitation [in Claim 109] of, "A composition comprising an enriched and expanded population of antigen-activated dendritic cells" in Claims 101 and 120 is not supported by the claims or specification as filed.

Also set forth previously, there is insufficient written description to show that Applicant was in possession of "a modified antigen", as recited in Claim 101, or the "antigen modification" of Claim 120.

Applicant arguments, filed 11/17/04, have been fully considered but are not found persuasive. Applicant argues that Examples 1-3 provide support for the invention as claimed. Applicant argues that *Fundamental Immunology*, Paul, ed., 1993 teaches that T cells present only peptides of about 8-11 amino acids. As the BCG of the examples presumably comprise proteins larger that 8-11 amino acids, Applicant is presumably arguing that said proteins must be modified. Though Applicant never actually makes the previous argument, Applicant does argue that the specification discloses processing antigen including fragmentation.

As set forth previously, specific examples disclosing specific parameters, e.g., specific antigens, specific times, specific culture conditions etc., comprises insufficient support for the generic cells of the invention as broadly claimed. Also note that fragmented antigens would comprise only a subset of modified antigens, e.g., modified antigens could include antigens with insertions or deletions, as well as derivatized antigens. Thus, the disclosure comprises insufficient written support for the invention of the instant claims.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 84, 89, 91-92, 94-95, 99, 101, and 103-120 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45 and 46 of copending Application No. 10/287,813. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass antigen-activated dendritic cells.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant again requests that this rejection be held in abeyance until the finding of allowable subject matter.

8. Claims 110, 115, 118, and 119 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed, for the reasons of record. This is a new matter rejection.

As set forth previously, the specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) the recitation in Claim 110 of, "wherein the cell aggregates are subcultured about every 3 to 30 days."

B) the recitation in Claim 115 of, "wherein said modified antigen is presented by the dendritic cells on MHC class I and MHC class II."

C) the recitation in Claims 118 and 119 of, "wherein the dendritic cell precursors are cultured in the presence of antigen."

Applicant arguments, filed 11/17/04, have been fully considered but are not found persuasive. Applicant argues that support for A) can be found at pages 44-46 and 57 of the specification.

A review of the specification shows that these cites disclose only mouse dendritic cell precursors, specifically those derived from specific mouse strains, and not the generic dendritic cell precursors of the instant claims.

Regarding B) Applicant argues that the limitation would have been well known at the time of the invention.

Applicant is advised that obviousness (including that which would have been well known at the time of the invention) is not the standard for the introduction of new matter.

Regarding C) Applicant argues that support for the limitations can be found in Example 3 and at pages 36-39 of the specification.

Applicant is advised that the limitations of Example 3 would support only claims drawn to cells derived from the specific disclosed mouse strains, and not the generic dendritic cell precursors of the instant claims. Regarding the disclosure of pages 36-39, the specific time limitations are not disclosed there.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

12. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

2/2/08

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